

## AMENDMENT

In the Specification:

Kindly amend the Specification as follows:

Please substitute the following paragraph for the paragraph on page 7, lines 9-15 of the application:

B<sup>1</sup>  
New adjuvants, such as the RIBI™ Adjuvant System (RAS) have been designed to substitute highly purified bacterial components for *M. tuberculosis* in order to maintain the immune stimulatory properties of CFA without the side effects. A variation of RAS, DETOX™ adjuvant, is currently in clinical trials as a component of cancer vaccines (NCI-V98-1489, NCI-96-C-0139). Others, such as Hunter's TITERMAX™, which is has not been approved for clinical use but has been extensively characterized in animal systems, use completely synthetic compounds.--

Please substitute the following paragraph for the paragraph on page 12, lines 1-11 of the application:

B<sup>2</sup>  
The methods of the present invention may be practiced with any immuno-adjuvant or combination of immunoadjuvants, including those set forth in Appendix A. Particularly preferred immuno-adjuvants are those of microbial or crustacean (chitosan) derived products. These include the RIBI ADJUVANT SYSTEM™, Detox™, glycated chitosan, and TiterMax™. The RIBI ADJUVANT SYSTEM™ and its components are described in issued US Patents 4,436,727 and 4,866,034. Preferably, the immuno-adjuvant comprises a mycobacterial cell wall skeleton component (described in US patent 4,436,727) and a component derived from lipid A of a bacterial lipopolysaccharide. Most preferably, the lipid A component is de-3-O-acylated monophosphoryl lipid A (described in US Patent 4,912,094. Additional adjuvants for use with the present invention include CFA, BCG, chitosan, and IFA. Delivery of the immuno-adjuvant may be systemic or localized.--

Please substitute the following paragraph for the paragraph on page 29, lines 3-14 of the application:

B<sup>3</sup> ~~--~~PDT treatment of mice bearing the B16-F1 tumor was performed as previously described for the M1 rhabdomyosarcoma mouse tumor (Richter *et al.*, 1987; Richter *et al.*, 1988; Richter *et al.*, 1991). Each mouse was weighed, warmed under infrared light for less than 5 min to dilate the blood vessels, restrained, and injected intravenously (tail vein) with Verteporfin at a concentration of 1.0 mg/kg body weight using a 28G needle. Thirty minutes later, animals were restrained and half of the animals were injected intratumorally with 50  $\mu$ L of TITERMAX<sup>TM</sup> adjuvant (Sigma) prepared as an emulsion with sterile phosphate buffered saline (PBS) according to the manufacturers specifications. Animals were then exposed to a light dose of 100 J/cm<sup>2</sup> in a circular area encompassing the tumor of 1 cm diameter at 688 nm wavelength. The power density was 70 mW/cm<sup>2</sup> and resulted in treatment times of 24 min per animal. Following treatment, animals were monitored daily for tumor response.~~--~~

Please substitute the following paragraph for the paragraph on page 31, lines 25-26 of the application:

B<sup>4</sup> ~~--~~The assays may be performed using the commercial, experimental adjuvant, RIBI ADJUVANT SYSTEM<sup>TM</sup> (RAS) (Corixa) or DETOX B-SE<sup>TM</sup> (Corixa) and alum for comparison.~~--~~

Please substitute the following paragraph for the paragraph on page 32, lines 11-17 of the application:

B<sup>5</sup> ~~--~~Liposomal verteporfin is injected at a dosage of 14 mg/m<sup>2</sup> of body surface area, which is a higher dose than for treating AMD. One to three hours later, diode laser light is applied at a rate of approximately 200mW/cm<sup>2</sup> for a total dosage of 120-180J/cm<sup>2</sup> to the lesion being treated. The dosage of the DETOX<sup>TM</sup> adjuvant, which is injected into the lesion after PDT, provides in the range of 100-200 $\mu$ g of the cell wall skeleton component, and 20-30 $\mu$ g of the

monophosphoryl lipid A component. This procedure is carried out at approximately 2 week intervals. Preferably there are 3 treatments.

Please substitute the following paragraph for the paragraph on page 43, lines 22-27 of the application:

B6  
-i. **RIBI ADJUVANT SYSTEM™ (RAS)**  
4 components: (1) monophosphoryl lipid A (MPL); (2) trehalose dimycolate (TDM); (3) cell wall skeletons (CWS); (4) *S. typhimurium* mitogen (STM)  
Ribi ImmunoChem Research, Inc.  
<http://www.ribi.com/>

Please substitute the following paragraph for the paragraph on page 44, lines 8-13 of the application:

B7  
-v. **DETOX B-SE™** for investigational use is supplied in clear glass vials.  
Each vial contains: 145 micrograms CWS from *M. phlei*, 25 micrograms MPL from *S. minnesota* R595, 8.1 milligrams Squalane F, 0.38 milligrams Polysorbate 80 (USP/NF), 1.62 milligrams Soy Lecithin (NF), and 88 micrograms Sterile Water for Injection (USP)  
DETOX B-SE™ must be stored refrigerated between 2 and 8°C

Please substitute the following paragraph for the paragraph on page 45, lines 9-11 of the application:

B8  
-i. **TITERMAX™**  
CytRx Corporation  
<http://www.cytrx.com/>